ENVIRONMENT, SAFETY & HEALTH

SAFETY & HEALTH HAZARDS ALERT

Assistant Secretary for Environment, Safety & Health • U.S. Department of Energy • Washington, D.C. 20585

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Recent Bioassay Issues Highlight the Need for a Quality Program

Background

In December 1994, the Department of Energy (DOE) issued an Environment, Safety and Health, Safety and Health Hazards Alert (Issue No. 94-3). The Alert described a situation at a DOE site where bioassay samples for approximately 30 workers involved in a 1989-1991 job, were never properly analyzed. After discovering the bioassay samples, which had not been analyzed for 3 years, the samples were sent to an offsite laboratory. The site received results from this laboratory indicating positive bioassay results for half of the samples. The site then conducted a review of the laboratory's quality assurance program and questioned the validity of these results.

The Alert discussed how the site's internal dose evaluation program could not ensure the adequacy of workplace and personnel monitoring to properly assess, minimize, and control radiation exposure to workers involved in decontamination and decommissioning (D&D) activities. The Alert recommended that sites involved in D&D or other non-routine activities that include new or unique mixtures of radionuclides thoroughly evaluate both the workplace environment and site procedures to ensure their adequacy to properly assess, minimize, and control radiation exposure to workers involved in these activities.

Updated Information

Since the issuance of the Alert, the site had collected additional urine samples from the affected individuals and sent them to a different independent offsite laboratory. This laboratory reported positive results for the majority of the samples (24 out of 26 samples). The site reviewed this laboratory's data and questioned the validity of these results. The laboratory reevaluated the samples and the new results indicated only 1 out of 26 were positive. Additional urine samples were collected and sent to two offsite laboratories. In mid-1995, results were obtained from both laboratories indicating no positive results.

Due, in part, to the above discussed difficulties in obtaining credible bioassay results for the affected individuals, additional concerns have been raised regarding the site bioassay program and potential worker exposure:

- Information concerning worker exposures may have been intentionally concealed.
- Employees may not have been warned of the possible hazards present.
- Continuous air monitors may not have been adequate to properly detect the radionuclides present.
- Proper protective clothing may not have been adequate to protect against hazards present.
- Individuals may not have been notified of positive bioassay results.
- Inflated detection sensitivities may have been used for bioassay samples.
- Individuals may not have been sampled in accordance with the frequency requirements as specified in procedures.
- Bioassay samples may not have been processed and results reported in a timely manner.
- Samples may not have been analyzed for isotopes that were known to exist.
- Annual exposure reports may have not been provided to workers.

Recent Events

Subsequent to the above, the following events relating to bioassay issues have occurred at the site. Some of these events result from the site's efforts to evaluate backlogged bioassay samples.

- Results of a routine urine sample of a worker came back positive. Although the resulting assigned dose was a small percentage of the annual limit (220 millirem), it took the site almost 1 year to make a dose determination. Work place indicators in place at the time did not indicate an exposure.

- Results of two other worker's routine samples came back positive with resulting doses estimated between 0.5 - 3.0 rem. As in the above event, it took the site over 1 year to make a dose determination. Work place indicators in place at the time did not indicate an exposure.

- Other similar events have occurred as the site continues to receive backlogged sample analyses results.

- There have been several recent personnel contamination events. Although there were no resulting dose to workers associated with these events, the events highlighted the need for enhancement in the site's program for personnel and equipment contamination monitoring, communications between working groups, and worker adherence to work procedures.

Implications

These recent events have hindered the site's ability to resolve the worker's health and safety concerns associated with the bioassay program. The problems with the bioassay program and the failure of the site to come to closure with those problems have resulted in workers expressing conerns over the site's ability to protect their health and safety. These concerns have escalated to legal action and the site is taking additional steps to respond.

Actions Recommended

All sites are now required to be in full compliance with the provisions of Title 10 Code of Federal Regulations, Part 835, *Occupational Radiation Protection.*
A summary of requirements relating to bioassay programs is attached. Failure to comply with these provisions could result in a contractor being assessed a civil penalty or could result in criminal penalties being taken against the contractor.

It is imperative that all the individuals who need to be on a bioassay program are properly identified. However, to ensure that adequate resources are allocated to properly analyze and evaluate results of bioassay sampling in a timely manner (and to avoid backlogging of samples as was the case for the site discussed above), it is necessary for sites to make reasonable determinations for including individuals in a bioassay program based on their potential for exposure.

Each site should evaluate the adequacy of their bioassay programs with a focus on the adequacy of the program to meet the increased activities associated with D&D work. At a minimum the evaluation should include a comparison against the requirements listed in the attachment. In making this evaluation, it will be beneficial to refer to guidance which DOE issued for implementing an acceptable bioassay program. This guidance is contained in the DOE Implementation Guide, *G-10 CFR 835/C1 - Rev 1, Internal Dosimetry Program*.

For more information, contact Peter O'Connell, Office of Worker Protection Programs and Hazards Management, EH-52, at 301-903-5641.

This Safety & Health Hazards Alert is one in a series of publications issued by EH to share occupational safety and health information throughout the DOE complex. To be added to the Distribution List or to obtain copies of the publication, call **1-800-473-4375 or (301) 903-0449.** For additional information regarding the publications, call Mary Cunningham at **(301) 903-2072.**

Attachment

The following are requirements relating to bioassay programs which are found in Title 10 of the Code of Federal Regulations Part 835, *Occupational Radiation Protection*.

Individual facilities may have additional requirements because of the facilities' previous contractual obligation to comply with specific DOE Orders and Notices, such as DOE 5480.11, *Radiation Protection for Occupational Workers*, and DOE N 5480.11 *Extension of Radiological Control Manual*. Since these Orders and Notices do not apply to all facilities, the bioassay related requirements in these documents are not included in the following list.

Requirement number 1.

§ 835.209 Concentrations of radioactive material in air.

(c) The estimation of internal dose shall be based on bioassay data rather than air concentration values unless bioassay data are:

(1) unavailable;
(2) inadequate; or
(3) internal dose estimates based on representative air concentration values are demonstrated to be as or more accurate.

Requirement number 2.

§ 835.402 Individual monitoring.

(c) For the purpose of monitoring individual exposures to internal radiation, internal dose evaluation programs (including routine bioassay programs) shall be conducted for:

(1) Radiological workers who, under typical conditions, are likely to receive 0.1 rem (0.001 sievert) or more committed effective dose equivalent, and/or 5 rems (0.05 sievert) or more committed dose equivalent to any organ or tissue, from all occupational radionuclide intakes in a year;

(2) Declared pregnant workers likely to receive an intake resulting in a dose equivalent to the embryo/fetus in excess of 10 percent of the limit stated in § 835.206; or

Note: The limit specified in § 835.206 is as follows: § 835.206 Limits for the embryo/fetus.

(a) The dose equivalent limit for the embryo/fetus from the period of conception to birth, as a result of occupational exposure of a declared pregnant worker, is 0.5 rem (0.005 sievert).

(3) Minors and members of the public who are likely to receive, in 1 year, an intake resulting in a committed effective dose equivalent in excess of 50 percent of the limits stated in § 835.207 or § 835.208, respectively.

Note: The limits specified in § 835.207 or § 835.208 are:

§ 835.207 Limits for minors.
Any minor exposed to radiation and/or radioactive material during direct on-site access at a DOE site or facility shall not exceed 0.1 rem (0.001 sievert) total effective dose equivalent in a year.

§ 835.208 Limits for members of the public entering a controlled area.
Any member of the public exposed to radiation and/or radioactivematerial during direct on-site access at a DOE site or facility shall not exceed 0.1 rem (0.001 sievert) total effective dose equivalent in a year.

(d) Internal dose evaluation programs shall be adequate to demonstrate compliance with § 835.202.

Note: The dose limits specified in § 835.202 are as follows:

§ 835.202 Occupational exposure limits for general employees.

(a) The occupational exposure to general employees resulting from DOE activities, other than planned special exposures under § 835.204 and emergency exposure situations under § 835.1302, shall be controlled so the following annual limits are not exceeded:
(1) A total effective dose equivalent of 5 rems (0.05 sievert);
(2) The sum of the deep dose equivalent for external exposures and the committed dose equivalent to any organ or tissue other than the lens of the eye of 50 rems (0.5 sievert).

Requirement number 3.

§ 835.702 Individual monitoring records.

(a) Records shall be maintained to document doses received by all individuals for whom monitoring was required pursuant to § 835.402.
(b) The results of individual external and internal dose measurements that are performed, but are not required by § 835.402, shall be recorded.
(c) The records required by this section shall:
(1) Be sufficient to evaluate compliance with § 835.202;
(2) Be sufficient to provide dose information necessary to complete reports required by subpart I of this part and by Departmental requirements for occurrence reporting and processing;

(4) Include the following quantities for internal dose resulting from intakes received during the year:
(i) Committed effective dose equivalent;
(ii) Committed dose equivalent to any organ or tissue of concern; and
(iii) Estimated intake and identity of radionuclides.
(5) Include the following quantities for the summation of the external and internal dose:
(i) Total effective dose equivalent in a year;
(ii) For any organ or tissue assigned an internal dose during the year, the sum of the deep dose equivalent from external exposures and the committed dose equivalent to that organ or tissue; and
(iii) Cumulative total effective dose equivalent received from external and internal sources while employed at the site or facility, since January 1, 1989.
(6) Include the dose equivalent to the embryo/ fetus of a declared pregnant worker.

Requirement number 4.

§ 835.801 Reports to individuals.

(a) Radiation exposure data for individuals monitored in accordance with § 835.402 shall be reported as specified in this section. The information shall include the data required under § 835.702(c). Each notification and report shall be in writing and include: the DOE site or facility name, the name of the individual, and the individual's social security number or employee number.
(b) Upon the request from an individual terminating employment, records of exposure shall be provided to that individual as soon as the data are available, but not later than 90 days after termination. A written estimate of the radiation dose received by that employee based on available information shall be provided at the time of termination, if requested.
(c) Each DOE- or DOE-contractor-operated site or facility shall, on an annual basis, provide a radiation dose report to each individual monitored during the year at that site or facility in accordance with § 835.402.